

IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ROBERT TOWNSEND

Plaintiff,

v.

ALEX AZAR II, in his official capacity
as the Secretary of the Department of
Health and Human Services.

Defendant.

Case No. 20-cv-1210 (ALC)

(Hon. Andrew L. Carter)

Electronically Filed

MEMORANDUM OF LAW IN SUPPORT OF
PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

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Dated: June 26, 2020

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Plaintiff Robert Townsend respectfully files this motion for summary judgment on the grounds that collateral estoppel bars the Secretary of the Department of Health and Human Services (“Secretary”) from denying Mr. Townsend’s claims for Medicare coverage. Therefore, the coverage denial at issue in this case should be reversed.

I. PRELIMINARY STATEMENT

This is an administrative review case, the resolution of which turns solely on an issue of law. Mr. Townsend is suffering from a particularly lethal form of brain cancer known as glioblastoma multiforme (GBM). Even with the proven success of tumor treatment field therapy (TTFT), the two-year survival rate remains well below 50%.

So far, four Administrative Law Judges (ALJs) have concluded that TTFT should be covered for Mr. Townsend after he repeatedly litigated the issue of whether TTFT is a “medically reasonable and necessary” and a Medicare covered benefit for him. Three of those decisions have now become final and the fourth decision will become final on July 8, 2020 (absent appeal).

Inexplicably, a fifth ALJ concluded that the same treatment to the same person for the same condition was not medically reasonable and necessary or a covered Medicare benefit. The Secretary continues to force Mr. Townsend to re-litigate the identical issue during the time he should be spending with family and focusing on his health. This must stop.

II. PROCEDURAL HISTORY OF CASE

As noted above, Medicare ALJs found Mr. Townsend’s TTFT to be a Medicare covered benefit for him four times. For one case that was inexplicably denied by ALJ Butler on June 25, 2019, Mr. Townsend appealed his denied claims at issue here to the Medicare Appeals Council (“Council”).

Consistent with the delays experienced by beneficiaries in the Medicare appeal process, the

Council did not rule on Mr. Townsend’s appeal within the 90-day timeframe mandated by Congress. As a result, pursuant to regulations, Mr. Townsend filed an “escalation request” with the Council seeking a decision within 5 days or authorization to file suit in district court. The Council still did not issue a decision and Mr. Townsend subsequently sought judicial review with, ultimately, the filing of this suit on February 11, 2020 (Dkt. 1).

III. LEGAL BACKGROUND

Collateral estoppel (*i.e.*, “issue preclusion”) is a venerable common law doctrine that bars re-litigation of a legal or fact issue determined in a prior proceeding. Under the doctrine of collateral estoppel, “once an issue is actually and necessarily determined by a court of competent jurisdiction, that determination is conclusive in subsequent suits based on a different cause of action involving a party to the prior litigation.” *Montana v. United States*, 440 U.S. 147, 153-54 (1979).

Collateral estoppel serves the triple purposes of protecting litigants from the burden of re-litigating an identical issue against the same party, promoting judicial economy by preventing needless litigation, and encouraging reliance on adjudication by preventing inconsistent results. *See Allen v. McCurry*, 449 U.S. 90, 94 (1980); *Parklane Hosiery Co., Inc. v. Shore*, 439 U.S. 322, 326 (1978).

In the Second Circuit, a party is collaterally estopped from relitigating an issue if: “‘1) the identical issue was raised in a previous proceeding; 2) the issue was actually litigated and decided in the previous proceeding; 3) the party had a full and fair opportunity to litigate the issue; and 4) the resolution of the issue was necessary to support a valid and final judgment on the merits.’” *See, e.g., Boguslavsky v. Kaplan*, 159 F.3d 715, 720 (2d Cir. 1998) (citing *Interoceanica Corp. v. Sounds Pilots, Inc.*, 107 F.3d 86, 91 (2d Cir. 1997)). As shown herein, each requirement is satisfied in the instant case.

Parallel or concurrent litigation is common. Where there is parallel or concurrent litigation, the case that reaches finality first may have preclusive effect on the other. *See, e.g., Kline v. Burke Const. Co.*, 260 U.S. 226, 230 (1922); *Adkins v. Nestle Purina Petcare Co.*, 779 F.3d 481, 484 (7th Cir. 2015) (“The first to reach final decision can affect the other ... through rules of claim and issue preclusion (res judicata and collateral estoppel)”). In other words, a later-filed case that reaches finality first may have preclusive effect on earlier-filed, but still on-going litigation. For example, in *Chicago, R.I. & P. RY, Co., v. Elder*, 270 U.S. 611 (1926), the Supreme Court held:

Nor is it material that the action proceeding, in which the judgment, set up as an estoppel, is rendered, was brought after the commencement of the action or proceeding in which it is pleaded. ... Whenever a judgment is rendered in one of the courts and pleaded in the other the effect of that judgment is to be determined by the application of the principles of res judicata by the court in which the action is still pending in the orderly exercise of its jurisdiction, as it would determine any other question of fact or law arising in the progress of the case.

Id. at 615-16.¹

Because of the unique posture of the United States as a litigant, the Supreme Court has held that offensive, non-mutual collateral estoppel does not apply against the United States. *See U.S. v. Mendoza*, 464 U.S. 154, 163-164 (1984) (“The concerns underlying our disapproval of collateral estoppel against the government are for the most part inapplicable where mutuality is present, as in ... *Moser*.”). As a result, only a party to a prior proceeding with the government can assert collateral estoppel against the government. Indeed, the Supreme Court has affirmed the application of offensive, mutual collateral estoppel against the United States. *See, e.g., U.S. v. Moser*, 266 U.S.

¹ “Res judicata” is a legal doctrine incorporating the concepts of “claim preclusion” (formerly known as “merger” and “bar”) and “issue preclusion” (formerly known as “collateral estoppel”). The confusing use of these terms has led to modern efforts to limit “res judicata” to mean “claim preclusion” and to use the term “issue preclusion” instead of “collateral estoppel.” *See THE RESTATEMENT (SECOND) OF JUDGMENTS* (1982); *Migra v. Warren City School District Board of Education*, 465 U.S. 75, 77 n. 1 (1984).

236 (1924). The Second Circuit has discussed the Supreme Court's application of issue preclusion against the government. *See, e.g., Beneson v. Commissioner of Internal Revenue*, 910 F.3d 690, 697 (2d Cir. 2018) (“[n]evertheless, the Supreme Court has permitted government preclusion where, *inter alia*, parties opposing the government in the two lawsuits are the same”) (citing *U.S. v. Stauffer Chem. Co.*, 464 U.S. 165, 171-173 (1984)).

Here, Mr. Townsend is not seeking to collaterally estop the Secretary with respect to coverage for TTFT claims filed by any person other than himself. Instead, Mr. Townsend contends that he should not have to relitigate the same coverage issues against the Secretary that have already been finally and conclusively determined in his favor.

Proceedings giving rise to collateral estoppel are not limited to cases before federal or state courts. In *Astoria Federal Savings & Loan Assoc. v. Solimino*, the Supreme Court held:

We have long favored application of the common-law doctrines of collateral estoppel (as to issues) and res judicata (as to claims) to those determinations of administrative bodies that have attained finality. When an administrative agency is acting in a judicial capacity and resolves dispute issues of fact properly before it which the parties have had an adequate opportunity to litigate, the courts have not hesitated to apply res judicata to enforce repose. Such repose is justified on the sound and obvious principle of judicial policy that a losing litigant deserves no rematch after a defeat fairly suffered, in adversarial proceedings, on an issue identical in substance to the one he subsequently seeks to raise. To hold otherwise would, as a general matter, impose unjustifiably upon those who have already shouldered their burdens, and drain the resources of an adjudicatory system with disputes resisting resolution. The principle holds true when a court has resolved an issue, and should do so equally when the issue has been decided by an administrative agency, be it state or federal, which acts in a judicial capacity.

501 U.S. 104, 107-8 (1991) (internal citations omitted); *see also B & B Hardware, Inc. v. Hargis Indus., Inc.*, 135 S.Ct. 1293, 1302-03 (2015) (confirming that administrative decisions can be a basis for issue preclusion); *S.E.C. v. Hansen*, No. 13-Civ-1403 (VSB), 2017 WL 1298022 (S.D.N.Y. Mar. 31, 2017) at *4 (defendant collaterally estopped from denying claims against him based in part on administrative proceeding before the SEC).

The application of collateral estoppel based on agency determinations (even against agencies) has been affirmed in numerous cases. *See, e.g., Brewster v. Barnhart*, 145 Fed. App'x. 542 (6th Cir. 2005) (SSA ALJ collaterally estopped by prior ALJ's work determination); *Islam v. U.S. D.H.S.*, 136 F. Supp. 3d 1088 (N.D. Cal. 2015) (DHS collaterally estopped by prior immigration judge's determination); *Continental Can Co., U.S.A., v. Marshall*, 603 F.2d 590 (7th Cir. 1979) (DOL collaterally estopped by prior decisions of department); *Bowen v. United States*, 570 F.2d 1311, 1321-23 (7th Cir. 1978) (NTSB acting in judicial capacity in prior proceeding, plaintiff collaterally estopped); *Cannon v. U.S.*, 2019 WL 5550065 at *4-5 (S.D. Cal. October 28, 2019) (plaintiff collaterally estopped by ALJ decision that became final while district court case was pending).

The Supreme Court has endorsed the view that the application of collateral estoppel in administrative proceedings is presumed and “favored as a matter of general policy.” *See Astoria*, 501 U.S. at 108; 109. Indeed, “where a common-law principle is well established, as are the rules of preclusion, ...the courts may take it as given that Congress has legislated with an expectation that the principle will apply except ‘when a statutory purpose to the contrary is evident.’” *Id.* (internal citations omitted). Such a presumption will therefore hold in the absence of evidence rebutting the presumption in the form of Congressional intent.

No such evidence has been presented by the Secretary to rebut the presumption that, in this case, multiple final Department of Health and Human Services determinations can bar the relitigation of the issue of Medicare coverage of TTFT for Mr. Townsend.

In other cases that are ongoing, the Secretary has contended that *de novo* review precludes the application of collateral estoppel. There is no merit to that claim. Courts routinely apply collateral estoppel in matters subject to *de novo* consideration/review. Indeed, orders granting summary judgment based on collateral estoppel are subject to *de novo* appellate review. *See, e.g.,*

S.E.C. v. Monarch Funding Corp., 192 F.3d 295, 303 (2d Cir. 1999) (applying *de novo* review).

IV. **FACTUAL BACKGROUND**

Mr. Townsend sets forth the following background information. While it is not necessary to grant his motion, a discussion of the factual context may assist the Court in consideration of the issues.

A. **Tumor Treatment Field Therapy (TTFT)**

As noted previously, GBM is an unusually deadly type of brain cancer. Prior to the advent of TTFT, average life-expectancy from diagnosis was ~14-16 months, with only ~5% of patients living after 5 years.

More recently, treatment of GBM using alternating electric fields developed. This is known as tumor treatment field therapy (“TTFT”). Alternating electric fields interfere with tumor cell replication and have been shown to dramatically increase progression-free time frames and overall survival rates. TTFT has proven so effective that, in late 2014, a randomized clinical trial of TTFT was suspended because it was deemed unethical to withhold TTFT from the control group.² Moreover, in ground-breaking papers published in the *Journal of the American Medical Association* (JAMA) in 2015 and 2017 that resulted from the clinical trial, TTFT was shown to increase the 2-

² In much scientific research, study participants are randomly assigned to “control” and “test” groups. The “control” group does not receive the treatment being tested. In contrast, the “test” group does. Proceeding in this way facilitates the determination of which effects, if any, are the result of the tested treatment as opposed to normal variation among the study participants. During the course of a study, interim results are frequently measured to determine whether the study is proceeding as planned and whether any changes are needed. When the interim results indicate that the tested treatment has a significant effect on health or safety, either negative or positive, ethical guidelines dictate that the study should be halted. Thus, if the interim results indicate that the tested treatment was significantly more likely to result in death than the control group, the study would be halted and the treatment no longer given to the “test” group. Likewise, if the interim result indicated that the tested treatment was life-saving, the study would be halted and the treatment would be made available to the “control” group. In those circumstances, withholding the treatment from the “control” group would be unethical.

year survival rate of GBM patients by more than 38% and to nearly triple the five-year survival rate.³

TTFT, an FDA-approved device worn on the head, was the first significant advance in treating GBM in more than a decade. It has become the standard of care for treating GBM and essentially all major private insurers cover TTFT. TTFT extends GBM patients' lives, in some cases, by years. Between January 2016 and December 2018, at least 93 scientific papers were published demonstrating the effectiveness of TTFT. It has a level one recommendation in the National Comprehensive Cancer Network ("NCCN") guidelines, *i.e.*, there is consensus among the experts, based on a high level of evidence, that TTFT is a recommended intervention.

The sole supplier/manufacture of the equipment that delivers TTFT is Novocure, Inc. The Optune system is rented from Novocure on a monthly basis. Once a Medicare patient suffering from GBM is prescribed the system, they will have monthly claims for coverage.

B. The Medicare Claims Process

Because GBM requires ongoing treatment, patients treated with TTFT will have multiple claims for Medicare coverage. As in this case, claims are typically submitted every one to three months to reflect a patient's continued use of TTFT.

Claims submitted by beneficiaries enrolled in Original Medicare are subject to a five (5) level appeal process that can (and typically does) take more than a year. At issue in each stage of the process is whether the claim is a Medicare covered benefit/is reasonable and necessary for the beneficiary. The beneficiary begins by submitting a claim. *See* 42 C.F.R. §§ 405.920-928. If the

³ *See Stupp, et al.*, "MAINTENANCE THERAPY WITH TUMOR-TREATING FIELDS PLUS TEMOZOLOMIDE VS. TEMOZOLOMIDE ALONE FOR GLIOBLASTOMA: A RANDOMIZED CLINICAL TRIAL", JAMA, Vol. 314, No. 23, pgs. 2535-43 (Dec. 15, 2015); *Stupp, et al.*, "EFFECT OF TUMOR TREATING FIELDS PLUS MAINTENANCE TEMOZOLOMIDE VS. MAINTENANCE TEMOZOLOMIDE ALONE ON SURVIVAL IN PATIENTS WITH GLIOBLASTOMA", JAMA, Vol. 318, No. 23, pgs. 2306- 2316 (Dec.19, 2017).

claim is denied, the beneficiary can request “redetermination.” *See* 42 C.F.R. §§ 405.960-958. If the claim is still denied, the beneficiary can request “reconsideration.” *See* 42 C.F.R. §§ 405.960-978.

If the claim is still denied, the Secretary is required to provide “hearings” for appeals to the “same extent” as is provided for in Social Security Hearings. *See* 42 U.S.C. § 1395ff(b)(1)(A) (citing 42 U.S.C. § 405(b)). That is, in conducting the hearings, the Secretary is authorized to administer oaths, examine witnesses, and receive evidence. ALJs may also make determinations on-the-record, unless CMS or a contractor elects to participate as a party in the hearing. *See* 42 C.F.R. § 405.1000(g).

The Secretary has promulgated regulations concerning the conduct of the “hearing” by ALJs. *See* 42 C.F.R. §§ 405.1000-1058. Where the beneficiary is represented by counsel, as in Mr. Townsend’s case, the hearings are adversarial. In such a case, the Secretary’s representative (in the form of the Centers for Medicare and Medicaid Services (CMS) or a “contractor” to Medicare) has the opportunity to litigate as a party. *See* 42 C.F.R. §§ 405.1008 and 405.1010.

In that capacity, the Secretary (like the beneficiary) can submit evidence (42 C.F.R. § 405.1018); object to the timing of the hearing (42 C.F.R. § 405.1020); object to the issues before the ALJ (42 C.F.R. § 405.1024); present evidence in the form of documents and witnesses (including through subpoenas); cross-examine witnesses, and present an argument (42 C.F.R. § 405.1036); and take discovery (42 C.F.R. § 405.1037). After the hearing, the ALJ issues a written decision that includes findings of fact, conclusions of law, and the reasoning, based on the evidence admitted at the hearing. *See* 42 C.F.R. § 405.1046.

Like the beneficiary, if the Secretary is dissatisfied with the ALJ’s decision, the Secretary can appeal to the Council. *See* 42 C.F.R. §§ 405.1100-1140. Regardless of whether the Secretary

chooses to participate in the hearing, the Secretary can appeal an ALJ's decision on "own motion" review. *See* 42 C.F.R. § 405.1110. An appeal to the Council (either direct or on "own motion" review) must be made within 60 days of the adverse ALJ decision. *See* 42 C.F.R. § 405.1110(a) and (b)(2).

Finally, if the beneficiary is dissatisfied with a decision from the Council, they can seek judicial review. *See* 42 U.S.C. § 1395ff(b)(1)(A) (*citing* 42 U.S.C. § 405(g)).

Although the statutes and regulations require both ALJs and the Council to issue decisions within 90 days, those deadlines are routinely missed. *See, e.g.*, 42 U.S.C. § 1395ff(d)(2). Thus, Medicare beneficiaries seeking coverage are often thrown into a multi-year effort to obtain coverage or at least get a decision on each denied claim before seeking relief in a federal court.

C. Mr. Townsend

Plaintiff Robert Townsend is a 56-year-old widower and life-long resident of Bronx. Prior to his diagnosis with GBM in 2011, Mr. Townsend was the primary caregiver to his three grandchildren. An avid sportsman and health advocate, Mr. Townsend was active in motorcycle and bicycle sports (racing and repair), volleyball, hand ball, and paddle ball. Among his many activities, Mr. Townsend enjoyed kayaking on the Hudson river. Since his diagnosis with GBM, in addition to spending time with his family members, Mr. Townsend enjoys volunteering with and supporting his church. He has been living close to nine years with a disease that has a five-year survival rate of ~5%..

After undergoing surgery, a standard course of chemo-radiation and additional courses of two different chemotherapy agents, Mr. Townsend was prescribed a TTFT device to treat his GBM.

V. STATEMENT OF RELEVANT MATERIAL FACTS

As detailed above, Mr. Townsend has three final decisions finding that TTFT is a Medicare covered benefit/“medically reasonable and necessary” for Mr. Townsend. An additional decision finding the same will become final on July 8, 2020 (absent an appeal by the Secretary). Inexplicably, one judge determined that TTFT was not a covered benefit for Mr. Townsend/not “medically reasonable and necessary”. Mr. Townsend was represented by counsel before each ALJ in cases where coverage was granted (SUMF⁴ ¶¶4, 14, 32, 41.)

November 8, 2018 Judge Krane Decision Granting Coverage

On November 8, 2018, ALJ David Krane issued a decision favorable to Mr. Townsend in ALJ Appeal No. 1-7737575148 for the months August - October 2017. (*Id.* ¶¶5-6.) The issue before Judge Krane was whether TTFT is “medically reasonable and necessary” for Townsend and a Medicare covered benefit for him. (*Id.* ¶¶9-10.) Judge Krane held, among other things, that:

the Optune device using tumor treatment field therapy was medically reasonable and necessary for the treatment of the Enrollee’s glioblastoma...;

[t]his decision is fully favorable for the Appellant. ... The Medicare contractor is directed to process the claim in accordance with this decision.

(*Id.* ¶¶11-12.) The Secretary did not appeal Judge Krane’s decision. (*Id.* ¶13.)

February 4, 2019 Judge Tyler Decision Granting Coverage

On February 4, 2019, ALJ Thomas Tyler issued a decision favorable to Mr. Townsend in ALJ Appeal No. 1-8116629727 for the months February - April 2018. (*Id.* ¶¶15, 18.) The issue before Judge Tyler was whether TTFT is a Medicare covered benefit for Mr. Townsend. (*Id.* ¶¶21.) Judge Tyler issued a decision on-the-record after originally notifying Mr. Townsend and the Secretary’s contractor C2C Innovative Solutions, Inc. of a hearing date. (*Id.* ¶¶16-17). Judge Tyler

⁴ SUMF = Plaintiff’s Statement of Undisputed Material Facts, filed contemporaneously herewith.

held, among other things, that:

the undersigned concludes as a matter of law that the Optune Tumor Treatment Field Therapy services were shown to be medically reasonable and necessary...;

and

the Medicare requirements have been met. Accordingly, the ALJ finds that the TTFT treatment provided to [Mr. Townsend] in this case are covered under Medicare Part B.

(*Id.* ¶¶22-23.) The Secretary did not appeal Judge Tyler’s decision. (*Id.* ¶24.)

June 25, 2019 ALJ Butler Decision Denying Coverage

Inexplicably, on June 25, 2019, ALJ Brian Butler issued an inconsistent decision in ALJ Appeal No. 1-8429561876 denying coverage of Mr. Townsend’s TTFT for dates of service August - October 2018. (*Id.* ¶¶25-26). The issue before Judge Butler was whether TTFT is a Medicare covered benefit for Mr. Townsend (“[t]he issue is whether use of the TTFT...to assist with the treatment/management of the Appellant’s glioblastoma is covered under Medicare Part B...”). (*Id.* ¶28.) Judge Butler found that TTFT is not a Medicare covered benefit for Mr. Townsend and explicitly held that it is not reasonable and necessary for him. (*Id.* ¶29 (“...the documentation does not substantiate that the Optune device was reasonable and necessary treatment for recurrent GBM.”); *id.* ¶30 (“[t]herefore, payment shall not be made under Medicare Part B for use of the Optune device...”). Mr. Townsend appealed the decision that TTFT is not a Medicare covered benefit to the Medicare Appeals Council, attaching the Judge Krane and Judge Tyler decisions thereto. (*Id.* ¶51.) After the Council failed to issue a ruling within 90 days as required upon his timely appeal, Mr. Townsend requested “escalation” pursuant to 42 C.F.R. § 405.1132. (*Id.* ¶52.) Mr. Townsend provided therewith the additional final ALJ decision from Judge Gates finding TTFT to be a Medicare covered benefit for him. (*Id.* ¶53.)

August 15, 2019 ALJ Gates Decision Granting Coverage

Notably, on August 15, 2019, ALJ Timothy Gates issued a favorable decision for Mr. Townsend in ALJ Appeal No. 1-8637672132 for months of service November 2018 – January 2019. (*Id.* ¶¶33-34.) The issue before Judge Gates was whether TTFT is a Medicare covered benefit for Mr. Townsend. (*Id.* ¶37). Judge Gates held that:

the record clearly establishes that the device is medically reasonable and necessary to treat [Mr. Townsend's] condition. . . .;

the electronic stimulation device (E0766) furnished to [Mr. Townsend]...is covered by Medicare.

(*Id.* ¶¶38-39.) The Secretary did not appeal Judge Gates' decision. (*Id.* ¶40.)

May 4, 2020 ALJ Cohn-Morros Decision Granting Coverage

On May 4, 2020, ALJ Carolyn Cohn-Morros issued a decision favorable to Mr. Townsend in ALJ Appeal No. 3-9212587609 for dates of service May – August 2019. (*Id.* ¶¶42-43.) The issue before ALJ Cohn-Morros was whether TTFT is a Medicare covered benefit for Mr. Townsend. (*Id.* ¶46). Judge Cohn-Morros held, among other things, that:

[t]his device was medically necessary pursuant to the FDA research and guidelines, the overwhelming medical data submitted by [Mr. Townsend], and Section 1862(a)(1) of the Social Security Act.; and

[Mr. Townsend] is entitled to coverage for the TTFT (E0766) provided on May 7, 2019, June 7, 2019, July 7, 2019, and August 7, 2019.

(*Id.* ¶¶47-48.) The Secretary has not yet appealed Judge Cohn-Morros' decision, and it will become final on July 8, 2020 absent such an appeal. (*Id.* ¶49.)

Because the Secretary did not appeal or reopen three of the four favorable ALJ decisions, they have become final. *See* 42 C.F.R. § 405.1048(a)(1)-(2).

VI. ARGUMENT

As a result of the three final decisions (and one decision that will be final on July 8, 2020

absent appeal) finding TTFT to be “medically reasonable and necessary”/a covered Medicare benefit for Mr. Townsend, the Secretary is collaterally estopped from denying that TTFT is “medically reasonable and necessary” and a Medicare covered benefit for him. Pursuant to 42 U.S.C. § 405(g) (fourth sentence), the Court should reverse the Secretary’s denial, order coverage, and remand this case with instructions to the Secretary to effectuate the Court’s decision.

A. The Court May Take Judicial Notice of Judge Cohn-Morros’ Decision & Proceedings Before Judge Tyler

Before turning to the elements of collateral estoppel, addressing an issue that is related to the Record will facilitate the Court’s consideration of this Motion. Notably, 42 U.S.C. § 405(g) (as modified by 42 U.S.C. 1395ff(b)(1)(A)) provides:

The court shall have the power, to enter, upon the pleadings and transcript of the record, a judgment affirming, modifying, or reversing [the Secretary] with or without the cause for a rehearing.

Mr. Townsend believes that this Motion can be granted relying solely on the three favorable decisions in the record. In this case, it is undisputed that these decisions are part of the Record. (See SUMF ¶¶ 5, 15, 33.)

In addition, this Court may properly take judicial notice of the decision in ALJ Cohn-Morros’ case as part of the “pleadings” in this case or simply as facts having independent legal significance. For example, in highly similar circumstances, the Seventh Circuit took judicial notice of other proceedings, vacating an agency determination. *Opoka v. INS*, 94 F.3d 392 (7th Cir. 1996). There, the Court was “limited to reviewing the evidence that was before the BIA[] at the time it made its decision” in Mr. Opoka’s deportation case. *Id.* at 394. However, after the BIA proceeding concluded, a relevant decision in another proceeding, his wife’s deportation case, issued. *Id.* (“After Mr. Opoka’s proceedings were concluded by the BIA, Mrs. Opoka was granted a suspension of deportation.”). Not only did the Seventh Circuit take judicial notice of the later

proceedings to vacate and remand the BIA decision, the Seventh Circuit held it would be “derelict” in its duty if it did not. *Id.* at 394-95. *See also, Golden Hill Paugussett Tribe of Indians v. Rell*, 463 F.Supp.2d 192, 197 (D. Conn. 2006) (court took judicial notice of Board of Indian Appeals decision regarding tribal status that became final after the filing of the case at hand, holding that the decision precluded the tribe from claiming tribal status in its action seeking to nullify conveyances of land).

Just as in *Opoka*, ALJ Cohn-Morros’ decision issued after this suit was filed and thus could not have been made part of the record. ALJ Cohn-Morros found TTFT to be medically reasonable and necessary and a covered Medicare benefit for Mr. Townsend. As discussed above, these are the same issues present in all the ALJ decisions in the record.

Additionally, to avoid any possible doubt, Mr. Townsend is submitting materials related to the proceedings resulting in ALJ Tyler’s decision. In particular, Mr. Townsend is submitting the Notices of Hearing issued by ALJ Tyler. Because of the manner in which it may arise, judicial notice of other proceedings/decisions giving rise to collateral estoppel is common. *See, e.g., Poindexter v. Cash Money Records*, No. 13-Civ-1155, 2014 WL 818955 at *3 (S.D.N.Y. Mar. 3, 2014) (judicial notice of prior determination that plaintiff was not a valid copyright owner in precluding infringement claim); *Lobo v. Celebrity Cruises, Inc.*, 704 F.3d 882, 892-93 (11th Cir. 2013) (judicial notice of entry of judgment in related proceeding supporting collateral estoppel); *Ross v. Meyer*, 741 Fed.Appx. 56, 59 (3d Cir. 2018) (judicial notice of decisions in parallel proceedings).

Thus, taking judicial notice of Judge Cohn-Morros’ decision and Judge Tyler’s Notice of Hearing as “pleadings” or facts having independent legal significance.

B. Collateral Estoppel Bars the Secretary from Denying Coverage for Mr. Townsend’s TTFT Claims

As three final decisions and an additional decision that is scheduled to become final on July 8, 2020 (absent appeal) found TTFT to be “medically reasonable and necessary” and a covered Medicare benefit for Mr. Townsend, the Secretary is collaterally estopped from relitigating the same issues.

1. The Issue Sought to Be Precluded is Identical to That Raised in Previous Proceedings

In the Medicare program, devices and services that are not “medically reasonable and necessary” are excluded from coverage. 42 U.S.C. § 1395y(a)(1)(A). Thus, whenever a coverage decision has finally determined that a device/service is a Medicare covered benefit, it has necessarily determined that the device/service is medically reasonable and necessary for that particular beneficiary.

In the present case, Mr. Townsend seeks to preclude the Secretary from denying that TTFT is a Medicare covered benefit for him (and the sub-issue of whether TTFT is “medically reasonable and necessary” for him).

As noted above, in three final decisions on separate claims brought by Mr. Townsend (and one decision that will be final on July 8, 2020 absent appeal), the ALJs decided the exact same issues of whether TTFT was a Medicare covered benefit for Mr. Townsend (and the sub-issue of whether it is “medically reasonable and necessary”). For instance, the issue before Judge Krane in 1-7737575148 was “whether the Appellant established the requirements for Medicare coverage.” *See* SUMF ¶10. Judge Krane then determined that TTFT was “medically reasonable and necessary”/a covered Medicare benefit for Mr. Townsend. (*Id.* ¶¶11-12.) This same issue was addressed in ALJ Tyler’, Gates’, and Cohn-Morros’ decisions granting coverage and litigated again in ALJ Butler’s

decision of June 25, 2019 decision denying coverage.

Specifically, in the denial here, the identical issue was presented and decided in the exactly opposite way. *See* June 25, 2019 Butler Decision issue (“[t]he issue is whether use of the TTFT...to assist with the treatment/management of the Appellant’s glioblastoma is covered under Medicare Part B...” (*Id.* ¶28); (*id.* ¶29 (“...the documentation does not substantiate that the Optune device was reasonable and necessary treatment for recurrent GBM”); (*id.* ¶30 (“[t]herefore, payment shall not be made under Medicare Part B for use of the Optune device...”)).

To the extent the Secretary contends that the issues are different because each decision covers different months, that is not well founded. As the Supreme Court noted in *Taylor v. Sturgell*, 553 U.S. 880, 892 (2008), issue preclusion bars successive litigation “even if the issue recurs in the context of a different claim.” It is well settled that the test for determining whether facts/issues are the same between two decisions for collateral estoppel purposes is “materiality.” That is, facts/issues are the same unless they are materially different with respect to the conclusions reached (*i.e.*, “changed circumstances”). *See, e.g., Montana v. U.S.*, 440 U.S. 147, 159 (1979) (“changes in facts essential to a judgment will render collateral estoppel inapplicable”); *Bernstein v. Bankert*, 733 F.3d 190, 226 (7th Cir. 2013) (“identical in all material aspects”); *Scooper Dooper, Inc., v. Kraftco Corp.*, 494 F.2d 840, 846 (3rd Cir. 1974). Thus, the fact that one decision concerns April 2018 (granting coverage) while another concerns August 2018 (denying coverage) is of no moment because there is no evidence that the month is material to the conclusions that TTFT was medically reasonable and necessary and a covered benefit for Mr. Townsend. There is no reference in the decisions that the basis of each decision hinges upon the particular months of service.

Indeed, collateral estoppel’s purpose in avoiding inconsistent results (*Allen*, 449 U.S. at 94; *Parklane*, 439 U.S. at 326.) is illustrated here. As noted, the decisions cover alternating months with

the following results:

August - October 2017	Covered (ALJ Krane)
February – April 2018	Covered (ALJ Tyler)
August – October 2018	Not Covered (ALJ Butler)
November 2018 – January 2019	Covered (ALJ Gates)
May 2019 – August 2019	Covered (ALJ Cohn-Morros)

Thus, in all TTFT claims brought by Mr. Townsend, the identical determinative issue was presented and decided.

Further, the fact that ALJ Gates’ decision issued after the decision of ALJ Butler is no bar to the application of collateral estoppel. Because the Secretary did not appeal the decision in Mr. Townsend’s favor, ALJ Gates’ decision has become final. By contrast, ALJ Butler’s decision is not final because it is the object of this appeal. As noted by the Supreme Court in *Elder*, where there is parallel/concurrent litigation, whichever case reaches finality first may have preclusive effect in the still pending case. *Elder*, 270 U.S. at 615-16. Here, ALJ Gates’ decision reached finality before ALJ Butler’s and, therefore, should have preclusive effect. Once the Secretary elected to allow favorable decisions for Mr. Townsend to become final three times, he should be estopped from continuing to litigate that identical issue in this case.

2. The Issue was Actually Litigated and Decided in the Previous Proceedings

As noted by another court in this Circuit, an issue is actually litigated if it is “‘properly raised by the pleadings or otherwise placed in issue.’” *Cerny v. Rayburn*, 972 F.Supp.2d 308, 318 (E.D.N.Y. 2013) (quoting *Evans v. Ottimo*, 469 F.3d 278, 282 (2d Cir. 2006)) (analyzing whether a bankruptcy court’s determination regarding a sale could bar federal claims related to the same issue). Indeed, the actual litigation requirement helps “ensure that a finding was carefully considered in the

first action, and that it therefore may serve as a fair basis for estoppel.” *S.E.C. v. Monarch Funding Corp.*, 192 F.3d 295, 309 (2d Cir. 1999). In finding that prior criminal sentences did not bar the defendant from relitigating his liability for securities fraud under collateral estoppel, the court noted that one issue, a potential ban from the securities industry, was not mentioned in either of the previous sentencing proceedings, suggesting that the issue was not actually litigated. *Id.* Necessarily, “when a court cannot ascertain what was litigated and decided, issue preclusion cannot operate.” *Id.* (quoting 18 James W. Moore et al., *Moore’s Federal Practice* § 132.03(2)(g) (3d ed. 1998)).

Here, the same issue was carefully considered and decided in each of the favorable cases. Mr. Townsend sought Medicare coverage for his TTFT in each of the four favorable cases. *See, e.g.*, SUMF ¶35 (Judge Gates) (Mr. Townsend “seeks Medicare coverage for the device furnished to him...”). Mr. Townsend properly raised the issue of Medicare coverage of TTFT for himself by appealing the negative QIC decisions. *See, e.g., id.* ¶36 (Judge Gates).

Further, each ALJ actually determined that issue explicitly in rendering their favorable decisions. (See Sec. V above.) Thus, the issue of whether TTFT is “medically reasonable and necessary” and a Medicare covered benefit for Mr. Townsend was actually litigated before each ALJ.

3. There was a Full and Fair Opportunity to Litigate the Issue in the Prior Proceedings

As noted by another court in this Circuit, under federal collateral estoppel rules, essential to the consideration of a full and fair litigation opportunity is determining whether the party against whom collateral estoppel is raised “‘was fully able to raise the same factual or legal issues’ in the prior litigation.” *In re Qiao Lin*, 576 B.R. 32, 48 (Bankr. E.D.N.Y. 2017) (quoting *LaFleur v. Whitman*, 300 F.3d 256, 274 (2d Cir. 2002)).

Mr. Townsend was represented by counsel in the proceedings before Judges Krane (SUMF ¶4), Tyler (*id.* ¶14), Gates (*id.* ¶32) and Cohn-Morros (*id.* ¶41.) Because Mr. Townsend was a represented party, the Secretary’s representative (in the form of the Centers for Medicare and Medicaid Services (CMS) or a “contractor” to Medicare) had the opportunity to litigate as a party at the ALJ level. *See* 42 C.F.R. §§ 405.1008, 405.1010. In other words, the Secretary was “fully able” to litigate the issue of TTFT as a Medicare covered benefit in each action. As noted above, the Secretary could have objected to the timing of the hearing in each case, conducted discovery in each case, called witnesses during the hearings if held, submitted briefs, etc. The Secretary did none of those things and chose not to appear at the scheduled hearings nor appeal the determinations adverse to him.

Even in Judge Tyler’s on-the-record case that concluded without a hearing, a notice of hearing was sent to the Secretary’s designated representative, proving notice to the Secretary yet again that more claims for Mr. Townsend’s TTFT were on appeal. *See* SUMF ¶16. As noted above, the Medicare regulations permit ALJs to issue decisions without a hearing, provided that neither CMS nor its contractors have elected to appear. It follows that the Secretary, through his contractors, did not elect to participate in Judge Tyler’s case.

Moreover, the decisions forming the basis for collateral estoppel here are each those of ALJs and not lower levels of appeal (*e.g.*, reconsideration). Proceedings before the ALJ (and Council) are those of the Secretary acting in a “judicial capacity” and therefore provide a proper basis for invoking collateral estoppel. *See Astoria Federal Savings & Loan Assoc. v. Solimino*, 501 U.S. 104, 107-8 (1991) (“When an administrative agency is acting in a judicial capacity ...”); *U.S. v. Utah Construction & Mining Co.*, 384 U.S. 394 at 422 (“When an administrative agency is acting in a judicial capacity and resolved ...”).

It is fair to apply collateral estoppel against the Secretary when the Secretary had the full array of rights as a litigant, has imposed costs on Mr. Townsend, and, having lost, did not appeal, thereby allowing decisions adverse to himself to become final in proceedings before the Secretary's own department.

4. The Issue was Necessary to Support Valid and Final Judgments on the Merits

As detailed above, the issue being litigated in each of the four favorable determinations was whether TTFT is "medically reasonable and necessary" and a Medicare covered benefit for Mr. Townsend. Given that it is the determinative issue, the decision on it in each case is an essential part of each decision. Further, as detailed above, essential to the prior, final judgments was a determination that TTFT was "medically reasonable and necessary." Because something is a Medicare covered benefit only if it is "medically reasonable and necessary", that determination was critical to each judge's decision. Each judge explicitly decided the sub-issue of medical reasonableness and necessity. (SUMF ¶¶11, 22, 38, 47.)

Of course, three of the four favorable ALJ decisions being invoked for collateral estoppel are final decisions by ALJs within the jurisdiction of the Secretary's Department, and as mentioned above, the fourth will become final on July 8, 2020 (absent appeal). Thus, the validity of the judgments is beyond dispute. "A judgment is 'valid' when it has been rendered by a court of competent subject matter jurisdiction and the party against whom judgment is rendered either has submitted to the jurisdiction of the court or has been afforded adequate notice." *See O'Leary v. Liberty Mutual Ins. Co.*, 923 F.2d 1052, 1066 (3d Cir. 1991) (citing *Restatement of Judgments (Second)* §1 (1982)).

Likewise, that the Secretary did not appeal the favorable judgments and the fact that three of them have become final is also beyond dispute. *See* 70 Fed. Reg. 36386-7 (June 23, 2005) ("The

ALJs within the Office of Medicare Hearings and Appeals issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council[.]”); 42 C.F.R. § 405.1100(c) (“The Council issues a final decision . . .”); *see also Smith v. Berryhill*, 139 S.Ct. 1765, 1775-6 (2019) (under APA, action is “final” if it: 1) marks the consummation of the agency’s decision making process; and 2) is one by which rights have been determined or from which legal consequences will flow).

Thus, that TTFT is “medically reasonable and necessary” and a Medicare covered benefit for Mr. Townsend was necessary and critical to support valid and final judgments on the merits of his previous cases.

C. The Decision at Issue Should be Reversed and Coverage Ordered

In applying collateral estoppel against the Secretary with respect to the issue of whether TTFT is “medically reasonable and necessary” for Mr. Townsend and a Medicare covered benefit for Mr. Townsend, the decision at issue should be reversed. ALJ Butler’s denial is premised solely on the conclusion that TTFT is not “medically reasonable and necessary”/not a Medicare covered benefit for Mr. Townsend. That is, there is no other basis for the denial of coverage (*e.g.*, the beneficiary passed away). Thus, if the Secretary is collaterally estopped from re-litigating that issue, there is no reason coverage should be denied.

VII. CONCLUSION

For the reasons set forth above, the Secretary should be collaterally estopped from denying that TTFT is medically reasonable and necessary for Mr. Townsend and a Medicare covered benefit for him. Mr. Townsend respectfully asks this Court to enter an Order granting his Motion for Summary Judgment and, pursuant to 42 U.S.C. § 405(g) (fourth sentence), remand this matter to the Secretary with instruction to cover Mr. Townsend’s claims.

Respectfully submitted,

/s/ Geoffrey G. Young

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Dated: June 26, 2020

CERTIFICATE OF SERVICE

I, Geoffrey G. Young, certify that a true and correct copy of the foregoing Memorandum of Law in Support of Plaintiff's Motion for Summary Judgment was filed electronically on June 26, 2020, is available for viewing and downloading from the federal court's ECF/CM system, and will be automatically served upon registered counsel of record by ECF/CM.

/s/ Geoffrey G. Young
Geoffrey G. Young

IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ROBERT TOWNSEND

Plaintiff,

v.

ALEX AZAR II, in his official capacity
as the Secretary of the Department of
Health and Human Services.

Defendant.

Case No. 1:20-cv-01210-ALC

(Hon. Andrew L. Carter)

Electronically Filed

APPENDIX OF UNPUBLISHED OPINIONS
CITED IN SUPPORT OF
PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

1. *S.E.C. v. Hansen*, No. 13-Civ-1403 (VSB), 2017 WL 1298022 (S.D.N.Y. Mar. 31, 2017).
2. *Cannon v. U.S.*, 2019 WL 5550065 (S.D. Cal. October 28, 2019).
3. *Poindexter v. Cash Money Records*, No. 13-Civ-1155, 2014 WL 818955 (S.D.N.Y. Mar. 3, 2014).

Respectfully Submitted,

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